

Individual Safety Report



3169256-X-00-01

For use by user-facilities,
butors and manufacturers for
MANDATORY reporting

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Teva Pharmaceuticals USA

Form Approved by FDA on 2/23/95

Mr. report #	6065 - AR
UF/Dist report #	
FDA Use Only	

A. Patient information

1. Patient identifier In confidence	2. Age at time of event: Unknown Date of birth: Unknown	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight lbs or kgs
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B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)	<input type="checkbox"/> disability
<input checked="" type="checkbox"/> death 1/16/94 (m/day/yr)	<input type="checkbox"/> congenital anomaly
<input type="checkbox"/> life-threatening	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
<input type="checkbox"/> hospitalization-initial or prolonged	<input type="checkbox"/> other:

3. Date of event (m/day/yr) 1/16/94	4. Date of this report (m/day/yr) 9-Dec-1998
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5. Describe event or problem

The attorneys representing the Estate of [REDACTED] stated that the deceased died on January 16, 1994 as a result of taking ordinary doses of [REDACTED] brand Extra-Strength Acetaminophen in combination with her regular consumption of alcohol.

Additional information 16-Sep-1998:

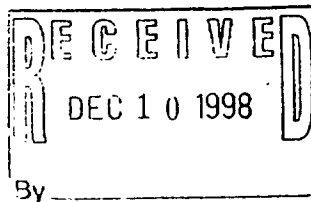
Follow-up information received in a summons from the attorney listed below indicated the patient had liver injury.

6. Relevant tests/laboratory data including dates

Not provided

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatorenal dysfunction, etc.)

Alcohol use.



3500A FACSIMILE

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)	
#1 Acetaminophen Caplets, 500 mg	
#2 Alcohol	
2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 Unknown	#1 Unknown
#2 Unknown	#2 Unknown
4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced
#1 Unknown	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
#2 Unknown	
6. Lot # (if known)	7. Exp. date (if known)
#1 2300	#1 ??-Jan-1996
#2 N/A	#2 N/A
8. Event reappeared after reintroduction	
#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
9. NDC # for product problems only (if known)	

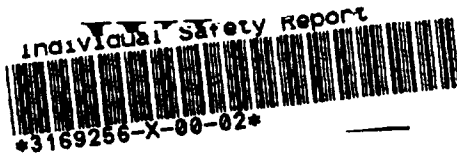
10. Concomitant medical products and therapy dates (exclude treatment of event)

G. All manufacturers

1. Contact office-name/address (a mailing site for devices)	2. Phone number (215) 256-8400
TEVA Pharmaceuticals USA 1510 Delp Drive Kulpsville, PA 19443	3. Report source (check all that apply)
	<input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input checked="" type="checkbox"/> consumer <input type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input checked="" type="checkbox"/> other Attorney
4. Date received by manufacturer (m/day/yr) 16-Sep-1998	5. (A)NDA # IND # PLA # pre-1938 <input type="checkbox"/> yes OTC product <input checked="" type="checkbox"/> yes
6. If IND, protocol #	7. Type of report (check all that apply)
	<input type="checkbox"/> 5-day <input checked="" type="checkbox"/> 15-day <input type="checkbox"/> 10-day <input type="checkbox"/> periodic <input type="checkbox"/> initial <input checked="" type="checkbox"/> follow-up # 1
8. Adverse Event term(s) Death Liver Damage	9. Mr. report number 6065-AR

E. Initial reporter

1. Name, address & phone #		
[REDACTED], Esquire [REDACTED] [REDACTED] [REDACTED]		
2. Health professional? <input type="checkbox"/> yes <input checked="" type="checkbox"/> no	3. Occupation Attorney	4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk



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Mfr. report #	6065
UP/Out report #	
FDA Use Only	

Continuation

Continuation for

C. Suspect Medications (continued):

1. [REDACTED] Sinus Tablets
2. Dose, frequency, and route used: Unknown
3. Therapy dates: Unknown
4. Diagnosis for use: Unknown
5. Lot #: P12604 Expiration date: ??-Aug-1996

RECEIVED
DEC 10 1998
By _____

DEC 11 1998